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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,183	03/16/2001	Robert W. Kreis	CV-0275	5218

26079 7590 12/28/2006
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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/719,183	KREIS ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action and Applicant's Arguments/Remarks, all filed 10/13/06 is acknowledged.

Claims 1 and 9-16 are pending in this action. No claims have been amended herein. Claims 2-8 have previously been cancelled. Claims 1 and 9-16 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer *et al.* (U.S. Pat. No. 5,899,893).

<>The instant invention is drawn to a method of treating an acute wound using a wound dressing as a substitute for a biological dressing or skin graft comprising the steps of:

a) applying the wound dressing to the wound; and

b) allowing the wound dressing to adhere to the wound for a period of time effective to promote epithelial outgrowth and promote vertical wicking into the dressing, wherein the wound dressing comprises highly absorbent fibers.

<>The instant invention is also drawn to a method of treating an acute wound using a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water comprising the steps of:

a) applying the wound dressing to the wound;

b) allowing the wound dressing to become adhered to the wound;

c) leaving the dressing in place until it dries out to form a crust; and

d) removing the dressing once the wound has healed.

<>The instant invention is also drawn to a method for substituting a wound dressing comprising highly absorbent fibers that can absorb at least 25 g/g of deionized water for a biological dressing comprising the steps of:

a) applying the wound dressing to a wound that would otherwise be treated using a biological dressing; and

b) allowing the wound dressing to adhere to the wound for a period of time effective to promote epithelial outgrowth and promote vertical wicking into the dressing, wherein the wound dressing comprises highly absorbent fibers.

Carlisle ('996) teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract).

According to Carlisle, the dressings have a finely porous, highly dense fibrous construction which provides the dual advantages of dispersing absorbed exudates to a low interlayer adhesion level, and preventing healing tissues from becoming entangled with the dressing's fibrous material (col. 3, lines 53-67). Carlisle teaches the significance of speed of absorption, direction of absorption and the length of wicking (col. 4, lines 1-14). The chart at

column 4 demonstrates that the dressing of Carlisle absorbs fluid steadily and continuously (i.e., wicking) (see col. 4, lines 15-55).

Carlisle teaches that the dressing layer materials can absorb distilled water vertically against gravity continuously for more than 5 hours (see claim 4). Carlisle also teaches that the dressing, when affixed and held in place with retaining material, adapts to exert relatively even pressure on the wound surface which tends to improve the quality of the repair tissue formed during healing (claim 17).

The wound dressings can be applied to wounds, such as burns (col. 2, lines 63-67).

Suitable dressing materials taught includes hard and soft wood pulp (col. 5, lines 19-22) and fibrous dense cellulose materials (see claims 1, 5, 6, 18).

With regards to the claim limitation 'for a period of time effective to promote epithelial outgrowth and promote vertical wicking' recited in instant claim 1, the Examiner notes that this limitation is a future-intended use limitation, which, without structural limitation, affords no patentable weight to the claims. Moreover the limitation, 'for a period of time effective to promote epithelial outgrowth and promote vertical wicking' is relative in terms of the time required in which epithelial outgrowth and/or vertical wicking occurs and the limitation fails to set forth any lower/upper parameters.

With regards to the amount of water (25 g/g) absorbed claimed in claims 12-15, Carlisle do not teach absorbing at least 25 g/g of deionized water. However, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is deemed obvious to one of ordinary skill in the art to determine suitable or effective amounts through routine or manipulative experimentation to obtain the best possible results, as these are indeed variable parameters attainable within the art. The particular method of treating an acute wound using a wound dressing and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle. Carlisle clearly teaches highly absorbent pressure dressings for wounds, such as burns, constructed from cellulosic, fibrous material, whereby the dressings are applied and affixed to curved surfaces of the human body.

In any event, **Dyer *et al.*** ('893) are relied upon for their teaching of absorbent articles, such as wound dressings, having a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g. Particularly preferred foam absorbents will wick at least about 45 g/g. The foam absorbents of the invention wick a high capacity of the test fluid to a particular height at equilibrium (see reference column 1, lines 11-19); (col. 2, line 45); (col. 7, lines 41-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the absorbent articles of Dyer *et al.* within the teachings of Carlisle. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Dyer *et al.* teach absorbent articles, particularly wound dressings and teach that their absorbent articles are able to wick at a high capacity at equilibrium, such as a vertical wicking capability of at least about 30 g/g, more preferably at least about 40 g/g and even at least about 45 g/g. The expected result would be a highly absorbent wound dressing that is beneficially used for the treatment of acute wounds.

Given the teachings of Carlisle and Dyer *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

- Bernardin *et al.* (U.S. Pat. No. 5,124,197):

  Bernardin *et al.* disclose absorbent cellulose fibers possessing improved vertical wicking properties (see Abstract).

Response to Arguments

Applicant's arguments filed 10/13/06 have been fully considered, but were not found to be persuasive.

- 35 U.S.C. §103(a) Rejection of claims 1 and 9-16 over Carlisle (U.S. Pat. No. 3,824,996) in view of Dyer et al. (U.S. Pat. No. 5,899,893):

Applicant argued "Carlisle is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting. Carlisle does not consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle, would not, therefore, motivate the person of ordinary skill to use a fibrous dressing as a substitute for a biological dressing."

Applicant's arguments have been considered, but were not found persuasive, since the arguments entail limitations that are directed to future-intended use or purpose. Carlisle teaches

dressings formed of a similar structure and function to that of Applicant's dressings. Carlisle teaches highly absorbent pressure dressings for wounds substantially constructed from cellulosic, fibrous material formed in thin layers and adapted to be applied and affixed to curved surfaces of the human body (see claims and Abstract). The reference also recognizes and teaches the importance of 'wicking' and teaches high absorption of fluids. It is the position of the Examiner that the particular method of treating an acute wound and applying the wound dressing to the wound would be obvious in view of the disclosure of Carlisle.

Applicant argued, "Applicant's dressings have been observed to promote migration of enzymes, neutrophils, fibroblasts and cellular debris into the dressing and this 'vertical wicking' (a direction perpendicular to the plane of the dressing) is thought to modulate the inflammatory response of the wound and contribute to healing."

Applicant's arguments have been considered, but were not found persuasive. Applicant's arguments that the "dressings have been observed to promote migration of enzymes, etc." do not entail the scope of claims being presented. The claims do not require the features addressed by Applicant.

Applicant argued, "The overall teaching of Carlisle is to make a dense laminar dressing that wicks laterally and bars the movement of exudates perpendicular to the plane of the dressing. Carlisle teaches away from Applicant's method wherein the dressing promotes vertical wicking and allows wound fluid to penetrate the whole dressing."

These arguments were not persuasive. The newly cited reference of Dyer *et al.* ('893) was relied upon to demonstrate the concept of vertical wicking in absorbent articles, such as wound dressings. Ample motivation has been provided by the combined reference teachings to

obtain a wound dressing that imparts and promotes vertical wicking, as similarly desired by Applicants.

Applicant argued, "Carlisle teaches dressings that require changing by delaminating the dressing and applying a new dressing. This teaches away from a dressing that becomes adhered to the wound and is left in place."

These arguments were not persuasive since Applicant's have not demonstrated any unexpected or superior results through the use of their wound dressing method steps over that of the prior art. The prior art is directed to the same field of endeavor to treat the same problems as that desired by Applicants. Moreover, the instant claims remain generic enough to read on the teachings of the cited art above.

Applicant argued, "Still a further difference is that to remove the dressing of Carlisle, we are told that the dressing must be saturated or provided with a wound contact layer".

This argument was not persuasive. The fact that the art's formulation may require one additional step versus that of the instant claims does not impart patentability to the claims.

Applicant argued, "The Action relies on Dyer, et al. to supply the deficiencies of Carlisle. However, there must be a suggestion in Carlisle to do so, and here there is none. As already noted, Carlisle teaches the high density of his dressing which is said to bar the passage of particles of greater than 25 microns through the fibrous structure. The exudate is spread laterally rather than vertically. The lateral spread enables the dressing to be delaminated and changed while on the wound. Carlisle sees no advantage in having vertical wicking. There is no motivation then to make the combination with Dyer, et al. Dyer, et al. disclose foams. There is no suggestion in Dyer, et al. that a fibrous core would be able to vertically wick.

Further, Dyer, et al. disclose at column 2, lines 11-24, that fibrous layers, when used to make catamenial absorbent structures, have a number of disadvantages. One is said to be topsheet dryness and another is rewet. Dyer, et al. thus suggest that it is not possible to make a

suitable absorbent structure from fibers, and this is why Dyer, et al. concentrate so fully on foams.

It is argued in the Office Action at page 9, first full paragraph, that: "Ample motivation has been provided by the combined reference teachings to obtain a wound dressing that imparts and promotes vertical wicking ..." However, again, there is no motivation in Carlisle to make a dressing that vertically wicks. Carlisle only provides motivation for lateral wicking. Dyer, et al. is not really directed at wound dressings but at sanitary napkins. The passages in Dyer, et al. concerning the disadvantages of fibers are all directed at problems with sanitary napkins. Dyer, et al. make no comment as to an advantage for vertical wicking in a wound dressing, particularly for use in the treatment of burns. Neither document provides any motivation to obtain a wound dressing that promotes vertical wicking."

These arguments were not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, while Carlisle teach lateral wicking, rather than vertical wicking, Dyer et al. are relied upon to demonstrate that it is well known in the art to employ absorbent articles, such as wound dressings that have vertical wicking capability. The argument that Dyer disclose disadvantages using fibrous layers was not persuasive since the primary reference initially teaches cellulosic fibrous materials and thus it is not required in the secondary reference. The Dyer et al. reference recognizes vertical wicking capability, albeit for preferred foam absorbents. The argument that 'Dyer et al. are not really directed at wound dressings, but at sanitary napkins' was not persuasive since absorbent articles

disclosed by Dyer et al. include wound dressings (see for instance, column 3, line 50 & claim 11 of Dyer). The argument that 'Dyer makes no comment as to an advantage for vertical wicking in a wound dressing' was not persuasive since the reference vividly suggests and teaches vertical wicking capability in absorbent articles, whereby wound dressings are listed as being amongst suitable absorbent articles for use in their invention. Thus, this is considered a positive teaching suggestion, which cannot be ignored in the art.

It remains the position of the Examiner that the instant claims are generic enough to read on the combined reference teachings of the art.

Given the explicit teachings of the cited art of record, the instant invention when taken as a whole, would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

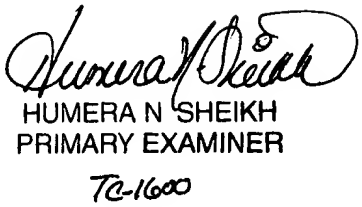
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

December 26, 2006



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